No. 17-1484

IN THE

Supreme Court of the United States

ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

ALLINA HEALTH SERVICES, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF THE AMERICAN HOSPITAL ASSOCIATION, FEDERATION OF AMERICAN HOSPITALS, AND ASSOCIATION OF AMERICAN MEDICAL COLLEGES AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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STATEMENT OF INTEREST

The American Hospital Association, Federation of American Hospitals, and Association of American Medical Colleges respectfully submit this brief as *amici curiae*.[1]

[1] No party or counsel for a party authored or paid for this brief in whole or in part, or made a monetary contribution to fund the brief's preparation or submission. No one other than *amici* or their members or counsel made a monetary contribution to the brief. All parties have consented to the filing of this brief.

The American Hospital Association (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. AHA members are committed to improving the health of the communities they serve and to helping ensure that care is available to and affordable for all Americans. The AHA educates its members on healthcare issues and advocates to ensure that their perspectives are considered in formulating health policy.

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. FAH's members include teaching and non-teaching hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. Dedicated to a market-based philosophy, the Federation provides representation and advocacy on behalf of its members to Congress, the Executive Branch, the judiciary, media, academia, accrediting organizations, and the public.

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 152 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The question presented here is of tremendous importance to *amici*'s members. The federal Medicare

program enables *amici*'s members to provide the wide range of critical healthcare services on which their patients and communities rely. And the patients and communities for whom this issue of Medicare administration matters most are among the country's most vulnerable.

By evading the notice-and-comment process required by 42 U.S.C. § 1395hh(a)(2), the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) were allowed to impose their own substantive policy views without understanding their direct impact on healthcare providers and those they serve. That procedural shortcut leads to policies that harm those affected by them, as well as inconsistency and uncertainty in how providers' Medicare reimbursements may be determined from year to year. Because "[n]otice and opportunity for comment are critically important for determining and meaningfully considering the true impact of any payment policy change on hospitals" (Br. in Opp. 38), the Court should affirm the judgment below.

SUMMARY OF ARGUMENT

I. Notice and comment is a mainstay of administrative law. Rightly so. Notice and comment is a critical procedural protection that enables public participation for those stakeholders most likely to be affected by contemplated agency policymaking and allows agencies' decisionmaking to be informed and responsive. To be sure, adding this additional layer of protection comes with certain trade-offs. But when an agency seeks to create, define, and regulate the rights, duties, and obligations of parties in a manner that entails substantial real-world impact,

notice and comment should be required. And for changes that alter the substantive legal standards governing Medicare payments, Congress has mandated precisely that. *See* 42 U.S.C. § 1395hh(a)(2).

The size and scope of the federal Medicare program demonstrate why notice and comment is essential for agency conduct altering payment policies. Even seemingly minor changes carry the potential for enormous consequences. The extensive history of this litigation, including CMS's repeated attempts to evade the specific payments due Respondents, reflects the stakes for agency action, even if the agency tries to underplay the significance of those actions. Had the proper procedures been followed from the outset, the parties and the public alike would have benefitted from the notice and comment Congress prescribed for exactly these circumstances.

II. Congress here required the opportunity for public participation through notice and comment before HHS and CMS could alter the Disproportionate Share Hospital (DSH) fraction calculations that determine the payments due providers under the DSH program. The text of Section 1395hh(a)(2), distinct from the Administrative Procedure Act (APA), extends to *any* change to the substantive legal standards governing Medicare payments. Petitioner's after-the-fact justification offered in defense of CMS's decision to forgo notice and comment by labeling its Medicare-fraction calculations "interpretive only" lacks merit.

That Congress required CMS to undertake notice and comment here does not mean CMS must *always* do so. Nor does the fact-sensitive decision below render the Medicare program unworkable more

broadly. True guidance documents, which instruct but do not dictate, need not go through notice and comment, as subsequent case law applying the decision below confirms. *See Clarian Health W., LLC* v. *Hargan*, 878 F.3d 346 (D.C. Cir. 2017). The decision below therefore will not upset HHS and CMS's administration of the Medicare program.

The Court should affirm the D.C. Circuit's judgment.

ARGUMENT

I. NOTICE AND COMMENT FOR SUBSTANTIVE LEGAL STANDARDS IMPLEMENTING THE MEDICARE ACT IS ESSENTIAL GIVEN MEDICARE'S SIZE AND SCOPE.

Congress required notice and comment for any "rule, requirement, or other statement of policy" that "changes a substantive legal standard governing" payments for Medicare services, 42 U.S.C. § 1395hh(a)(2), for good reason. When it comes to Medicare, seemingly small changes can have outsized results. This case is a perfect example. Whether Part C days count in the Medicare or Medicaid fraction has substantial real-world impact. That decision alone affects billions of dollars of federal funding according to the Government's own estimate. *See* Pet. 14. It is precisely the sort of substantive legal standard that should be subject to public input.

1. Medicare is a program of great importance to the health of our nation. Total Medicare benefits entailed more than $700 billion in federal spending in 2017, almost double the $425 billion spent in 2007. Juliette Cubaski & Tricia Neuman, *The Facts on Medicare Spending and Financing*, Henry J. Kaiser

Family Foundation (June 22, 2018).[2] Medicare expenditures were also 15 percent of total federal spending in 2017; by 2028, Medicare's share is expected to rise to 18 percent. *See id.* And Medicare alone accounts for roughly 20 percent of the $3.3 trillion a year spent on health care nationally. *See* Centers for Medicare & Medicare Servs., *National Health Expenditure Data: Historical* (Jan. 8, 2018).[3] In Calendar Year 2018, CMS estimates that an average of 59.1 million people will have received benefits under Parts A and B each month. Centers for Medicare & Medicare Servs., *CMS Fast Facts: CMS Program Data - Populations* (July 2018).[4]

With its growth, the Medicare program has become "a massive, complex health and safety program * * * embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations." *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). And its administration is difficult. "Over the years, HHS and CMS have come to appreciate their roles as regulatory and procurement agencies when it comes to the administration of the Medicare program. But the history of the program suggests that HHS and CMS did not come easily to this realization." *See* Eleanor D. Kinney, *The Accidental Administrative Law of the Medicare Program*, 15 Yale J. Health Policy, L. & Ethics 111, 138 (2015). Today, Medicare is "governed by a complex web of legislative rules, interpretive rules and manuals, policy guidance and computer pro-

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[2] *Available at* https://bit.ly/2BTku4o.

[3] *Available at* https://go.cms.gov/1Jy5kin.

[4] *Available at* https://go.cms.gov/1JjCGaC.

grams" that "guide a host of decisions" concerning the program's operations. *Id.* at 111. As a result, even seemingly small tweaks to a subcomponent of the Medicare program can have far-reaching consequences.

2. The saga of the policy at issue here—whether Part C managed-care patients should be counted as entitled to benefits under the Part A fee-for-service component of the Medicare program—exemplify why Congress wanted public input on all substantive standards. The DSH adjustment is just one part of the constantly changing and "byzantine process" that governs Medicare payments to hospitals. *Billings Clinic* v. *Azar*, 901 F.3d 301, 309-311 (D.C. Cir. 2018); *accord Schweiker* v. *Gray Panthers*, 453 U.S. 34, 43 (1981) (describing the Medicare program as "Byzantine" and "among the most intricate ever drafted by Congress."). Similarly "byzantine" is the process for determining the "Medicare and Medicaid fractions" used to "provide a proxy for the total low-income patient percentage" when calculating the DSH adjustment itself. *Catholic Health Initiatives Iowa Corp.* v. *Sebelius*, 718 F.3d 914, 916 (D.C. Cir. 2013). "Many aspects of the DSH adjustment have been challenged over the years," *see id.* at 917, as would be expected given this complexity and the Government's shifting understanding of that legal landscape.

Whether Part C days are included in the Medicare or Medicaid fraction may *seem* like a minor issue. But it has far-reaching effects. As Petitioner stressed in its bid for this Court's review, the status of Part C days implicates $3 to $4 billion in Medicare spending that supports the work of hospitals that disproportionately serve vulnerable populations. *See*

Pet. 14. And for the individual hospitals whose funding turns on that determination, "the practical consequences of this dispute number in the hundreds of millions of dollars." *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 5 (D.C. Cir. 2011); *accord Allina Health Servs.* v. *Sebelius*, 746 F.3d 1102, 1107 (D.C. Cir. 2014) (observing the "enormous financial consequences for the hospitals"). The effects go far beyond the financial, however, as that funding translates directly into a wide range of critical services for low-income patients. Given these effects, the determination to include Part C days in the Medicare or Medicaid fraction calls out for notice and comment like any other major policy change.

Petitioner argues that upholding the decision below would mire the Medicare system in red tape by subjecting every CMS decision to notice and comment. Pet. Br. 41-43. That concern is overblown, as we explain below. *Infra* pp. 19-22. Petitioner's true motive instead is to seek a special rule that allows CMS to avoid the DSH-adjustment payments due by changing a substantive legal standard governing the payment calculation without advance notice and comment. By recharacterizing as mere suggestions CMS's mandates to Medicare contractors, hospitals, and the Provider Reimbursement Review Board (PRRB), and then disclaiming Section 1395hh(a)(2)'s purportedly burdensome and unworkable notice-and-comment procedures, Petitioner is trying to escape CMS's payment obligations. The Court should not allow that to happen.

3. Notice and comment is not just the law. It also improves policy outcomes. This Court has long recognized that "fairness and deliberation" should

undergird any "administrative action with the effect of law." *United States* v. *Mead Corp.*, 533 U.S. 218, 230 (2001).

Notice and comment is the principal way "to assure due deliberation." *Smiley* v. *Citibank (S. Dakota), N.A.*, 517 U.S. 735, 741 (1996). And it serves two central purposes. First, providing for notice and comment directs the regulatory process "to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." *National Elec. Mfrs. Ass'n* v. *EPA*, 99 F.3d 1170, 1174 (D.C. Cir. 1996) (quoting *MCI Telecomms. Corp.* v. *FCC*, 57 F.3d 1136, 1141 (D.C. Cir. 1995)). Second, notice and comment "promot[es] informed agency action" by making sure that "'the agency will have before it the facts and information relevant to a particular administrative problem.'" *Id.* (quoting *MCI Telcomms.*, 57 F.3d at 1141). By guaranteeing both public participation and informed agency action, the notice-and-comment requirement works toward a better administrative process for all.

To be sure, the notice-and-comment process may require that agencies invest greater time and deliberation than they may otherwise be inclined to do. But in the Medicare context and outside of it, "[p]re-adoption notice-and-comment can be most helpful for significant guidance documents that are particularly complex, novel, consequential, or controversial." *See* Office of Mgmt. and Budget, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3438 (Jan. 25, 2007). And when "controlling effect" is given to agency conduct setting a substantive legal standard on issues of sufficient "importance," such rules should "be promulgated only following public

participation." Kevin W. Saunders, *Interpretative Rules with Legislative Effect: An Analysis and A Proposal for Public Participation*, 1986 Duke L.J. 346, 383 (1986).

Notice and comment helps not just the public, but also the courts. Just as notice and comment allows "the public * * * a chance to speak and be heard," it allows a reviewing court to assess whether "the public [was] *listened* to" and whether "its evidence and point of view" were considered. Eugene Scalia, Essay, *The Value of Public Participation in Rulemaking*, Penn. Reg. Rev. (Sept. 25, 2017) (emphasis in original).[5] That enables the federal courts to provide a meaningful check on administrative conduct and inject another layer of accountability into the process, which is critical to our constitutional framework. *See FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 536 (2009) (Kennedy, J., concurring) (explaining the importance of judicial review given "the administrative agency's unique constitutional position" as "the exact locus of its powers present questions that are delicate, subtle, and complex").

The Medicare program, too, benefits from notice and comment. By refusing to allow public participation on the challenged policy concerning the treatment of Part C patients in the Medicare and Medicaid fractions, CMS deprived itself and the public of the benefits of these statutorily mandated procedural protections. Indeed, had CMS opened up the decisionmaking process to public scrutiny rather than "pull a surprise switcheroo," *Allina Health Servs.*,

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[5] *Available at* https://bit.ly/2fKUoZk.

746 F.3d at 1108 (quoting *Environmental Integrity Project* v. *EPA*, 425 F.3d 992, 994 (D.C. Cir. 2005)), Respondents' resort to this torturous litigation may never have been necessary. When it works as intended, notice and comment catches mistakes before they are made. Without it—as here—it can lead to over a decade of litigation.

II. PETITIONER'S NEW POLICY ON PART C DAYS CHANGES A SUBSTANTIVE LEGAL STANDARD AND THEREFORE REQUIRED NOTICE AND COMMENT.

Petitioner argues that CMS's calculation of the so-called Medicare fraction—a portion of the formula that determines the DSH payment given to hospitals serving the most-vulnerable populations—did not require notice-and-comment rulemaking because it was merely a "nonbinding interpretation of a statute." *See* Pet. Br. 20-41. That litigation position is not only contrary to the Medicare Act, as described above, it is also at odds with the APA, and the contemporaneous views of CMS's own officials.

Further, it is contrary to the government's—including the current Administration's—view of the line between interpretive and legislative rules outside the Medicare context. The Department of Justice and other federal agencies have concluded that rules that create, define, and regulate the rights, duties, and obligations of parties—whatever their label—are substantive legal standards and must be subjected to notice and comment. CMS could not include Part C days in the Medicare fraction without first going through notice and comment.

A. Section 1395hh(a)(2) Required Notice and Comment Here.

1. Petitioner contends that Congress in Section 1395hh(a)(2) actually imported the APA, including its interpretive-rule exemption for notice and comment. Pet. Br. 22-28. But three different canons of construction counsel against that conclusion.

First, Congress did not import or cross-reference the APA's interpretive-rule exemption in Section 1395hh(a)(2). *Cf.* 42 U.S.C. § 7607(d) (stating that the Clean Air Act's rulemaking provisions "shall not apply in the case of any rule or circumstance referred to" in the APA's interpretive-rule exception). Congress "knew how to distinguish between regulations that have the force and effect of law and those that did not, but chose not to do so in" Section 1395hh(a)(2). *Department of Homeland Sec.* v. *MacLean*, 135 S. Ct. 913, 921 (2015).

Second, Petitioner's argument would result in Section 1395hh(a)(2)'s rulemaking provision meaning the exact same thing as the APA's, despite using different language. Yet the Court "refrain[s] from concluding * * * that the differing language * * * has the same meaning." *Russello* v. *United States*, 464 U.S. 16, 23 (1983).

Finally, the APA provides the "default" rules when an agency's organic act does not provide specific ones. *See National Petrochemical & Refiners Ass'n* v. *EPA*, 643 F.3d 958, 961 (D.C. Cir. 2011) (Brown, J., dissenting from denial of rehearing en banc) (noting the "default notice-and-comment procedures of the APA"). If Section 1395hh(a)(2) were to mean the exact same thing as the APA's rulemaking provision, then Congress would have had no reason to pass

Section 1395hh(a)(2). And this Court "requir[es] a change in language to be read, if possible, to have some effect." *American Nat'l Red Cross* v. *S.G.*, 505 U.S. 247, 263 (1992). Reading Section 1395hh(a)(2) to be congruent with the APA would make Congress's amendment adding the section a nullity.

2. For more than seventy years, the APA has governed federal agencies engaging in rulemaking. 60 Stat. 237 (1946). Under the APA, agencies must provide a public notice-and-comment period to "give interested persons an opportunity to participate in the rule making [process] through submission of written data, views, or arguments." 5 U.S.C. § 553(c). The APA distinguishes between "substantive" or "legislative" rules and "interpretive" rules. Generally speaking, promulgating "legislative" rules requires notice and comment, while "interpretive" rules do not. *Compare id.*, *with id.* § 553(d). But the APA does not define the difference between the two.

Despite decades of case law, the distinction between "legislative" and "interpretive" rules remains muddled. The "precise meaning" of the "term 'interpretative rule,' or 'interpretive rule,'" has been "the source of much scholarly and judicial debate." *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (declining to "wade into that debate"). The line is one that "'breeds bewilderment and frustration'" and has variously been called "'fuzzy,' 'tenuous,' 'baffling,' 'blurred,' and 'enshrouded in considerable smog'" by courts and commenters alike. *See* Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. Chi. L. Rev. 1705, 1708-09 (2007) (citations and footnotes omitted).

Congress enacted the Medicare Act's distinct notice-and-comment requirements—which direct HHS to engage in notice-and-comment rulemaking for any "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing * * * payment for services"—against this backdrop. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4035(b). Congress was concerned that "important polices [were] being developed without benefit of the public notice and comment period." H.R. Rep. No. 100-391, at 430 (1987).

So rather than rely on an amorphous distinction between legislative and interpretative rules, Congress laid down a bright line: *Any* HHS action—even one that is a mere "statement of policy"—that "establishes or changes a substantive legal standard" in the enumerated areas must go through notice and comment. *See* 42 U.S.C. § 1395hh(a)(2). Section 1395hh(a)(2)'s text reflects that congressional decision, declining to incorporate the APA's broad exemption for interpretative rules. *See* Pet. App. 12a.

Under the proper Section 1395hh(a)(2) standard, CMS's inclusion of Part C days in the Medicare fraction had to go through notice and comment. As the D.C. Circuit explained, CMS's inclusion of Part C days in the Medicare fraction was a "requirement" because CMS's contractors are required to use the fraction that CMS calculates when making DSH payment decisions. Pet. App. 12a. CMS's inclusion of Part C days in the fraction is also a change in standards because CMS previously *excluded* Part C days from the Medicare fraction. *Id.* at 13a. And CMS's inclusion of Part C days in the Medicare fraction is a substantive legal standard because it

"define[s] the scope of hospitals' legal rights to payment for treating low-income patients." *Id.* at 14a. The D.C. Circuit correctly concluded that CMS's inclusion of Part C days in the Medicare fraction had to undergo notice and comment.

3. Petitioner's contention that CMS's calculation of the Medicare fraction was merely nonbinding guidance falls all-the-more flat because CMS's own Provider Reimbursement Review Board (PRRB) understood the policy to bind it, not merely guide it.

The PRRB is an independent administrative forum that hears disputes concerning final reimbursement determinations made by CMS or by Medicare contractors. *See* 42 C.F.R. pt. 405, subpt. R; 42 U.S.C. § 1395oo(a); Pet. App. 25a. The PRRB is required to apply the Medicare Act, agency regulations, and CMS rulings. *See* 42 C.F.R. § 405.1867. But the PRRB need not follow "interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice." *Id.*

The PRRB can authorize expedited judicial review—allowing the appellant to skip over the PRRB portion of the Medicare appeals process—when "[t]he Board lacks the authority to decide a specific legal question" because it challenges "the substantive or procedural validity of a regulation or CMS ruling." *Id.* § 405.1842(f)(1)(ii). In other words, if the appellant's challenge goes to the validity of a substantive standard, the PRRB itself can authorize the appellant to bypass the Board's review. *See id.*

Here, in granting expedited judicial review of whether CMS's 2012 DSH calculations were procedurally invalid, the PRRB found it was bound by the vacated 2004 rule incorporating Part C patient days

as part of the Medicare fraction. Pet. App. 57a, 72a; *see also* Resp. Br. 16-17. The PRRB understood that "it is *bound* by the *regulation*," regardless of whether the regulation itself was "valid." Pet. App. 57a, 72a (emphases added). And what the Board did *not* say is equally important: had it viewed the decision as a nonbinding "interpretive rule" or "statement of policy," as Petitioner asserts it should have, the Board would have considered CMS's calculations but been free to deviate from them.

Importantly, the PRRB also granted expedited judicial review based upon its determination that it was "without the authority to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions * * * are legal." *Id.* Simply put, the PRRB concluded that it did not have authority to determine the legality of the agency's action following vacatur of the 2004 rule.

The PRRB's decision to grant expedited judicial review cannot be squared with Petitioner's made-for-litigation assertion that CMS had issued a "nonbinding interpret[ive]" standard only. Rather, the record belies that assertion. Not only were Respondents' arguments before the PRRB uncontested, the intermediary on the other side of Respondents' appeal did not oppose expedited review. *Id.* Further, the D.C. Circuit held that the PRRB properly concluded that expedited judicial review was warranted (Pet. App. 10a-11a), and Petitioner has not contested that finding in this Court. Thus, as the case comes to this Court, CMS's own independent adjudicators correctly determined that the inclusion of Part C days in the Medicare fraction was a binding standard.

That conclusion dramatically undercuts Petitioner's argument that the PRRB could have come to its own conclusion as to whether Part C days were properly included. This Court declines to credit agency litigating positions that are "wholly unsupported * * * by administrative practice," *Bowen* v. *Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988), and that are a "*post hoc* rationalization advanced by an agency seeking to defend past agency action against attack." *Christopher* v. *SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012) (citation, internal quotation marks, and brackets omitted). It should do so again and reject Petitioner's argument that the PRRB could have rejected CMS's inclusion of Part C days in the Medicare fraction.

4. Petitioner's contention that CMS's inclusion of Part C days in the Medicare fraction was merely a nonbinding interpretation is further undercut by the Government's own warnings against slapping the "interpretive" label on substantive legal standards.

The Office of Management and Budget in 2007 issued a best-practices document cautioning that "[e]xperience has shown" that interpretive documents "may be poorly designed or improperly implemented," and these "documents may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review," including notice and comment. 72 Fed. Reg. at 3432. As the D.C. Circuit has summarized the typical offending pattern: "Congress passes a broadly worded statute. The agency follows with regulations * * *. Then as years pass, * * * the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation." *Appa-*

lachian Power Co. v. *EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000).

That creation of substantive legal standards without advance notice and comment comes with serious consequences. As OMB further warned, "[c]oncern about whether agencies are properly observing the notice-and-comment requirements * * * has received significant attention. The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they initially are labeled." 72 Fed. Reg. at 3433; *see also* Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals and the Like-Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L.J. 1311 (1992); 72 Fed. Reg. at 3432 n.2.

Just this past year, the Department of Justice announced its own position that "interpretations" such as the one at issue here require notice and comment. The Attorney General cautioned in a November 2017 memorandum that "the Department has in the past published guidance documents—or similar instruments of future effect by other names, * * * —that effectively bind private parties without undergoing the rulemaking process." Mem. from Att'y Gen., U.S. Dep't of Justice 1 (Nov. 16, 2017).[6] He then announced that "[t]he Department will no longer engage in this practice. Effective immediately, Department components may not issue guidance docu-

[6] *Available at* https://bit.ly/2E2otkb.

ments that purport to create rights or obligations binding on persons or entities outside the Executive Branch." *Id.*

These problems with substantive standards adopted without notice and comment are precisely the ones Congress intended to solve when it enacted Section 1395hh(a)(2). When a policy such as the one offered by CMS here effectively binds regulated parties and agency officials alike, the agency must first go through proper notice-and-comment channels. Petitioner's attempt to relabel its policy a "nonbinding interpretation" is simply another instance of a rule masquerading as a guidance document. The Court should not countenance it.

B. The Government's Workability Concerns Are Overblown.

Petitioner contends that an "interpretation of Section 1395hh" giving effect to the statute's plain language "would substantially undermine HHS's ability to administer Medicare in a workable manner." *See* Pet. Br. 41-43. But Petitioner's administrability concerns are overblown. Not all CMS policies need go through notice and comment; just those, like the determination here, that substantively alter how providers are paid.

1. CMS need not engage notice and comment for true guidance documents that do not tie the hands of the agency or the PRRB. For instance, Petitioner frets that a ruling for Respondents will upend the Provider Reimbursement Manual. Pet. Br. 41-42. But this Court and others have repeatedly concluded that the Manual is merely an interpretive guide that does "not have the force and effect of law." *See, e.g.*, *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 99

(1995); *South Shore Hosp., Inc.* v. *Thompson*, 308 F.3d 91, 103 (1st Cir. 2002); *National Med. Enters.* v. *Bowen*, 851 F.2d 291, 293 (9th Cir. 1988); *see also Trust Under Will of Wills* v. *Burwell*, 306 F. Supp. 3d 684, 693 (E.D. Pa. 2018) (holding that comparative-volume consideration in a CMS Survey & Certification Memorandum provided only "some form of guidance as to how the legal standards are applied" when "the agency maintains the same authority to grant or deny applications as it would without a stated public policy"). The decision below does not challenge these consistent holdings.

CMS generally also need not put its policies through notice and comment when they can be disregarded by agency adjudicators like the PRRB. The PRRB can—and does—routinely reject CMS guidance as inconsistent with the Medicare Act or HHS regulations. *See, e.g.*, *Provena Health 2006 LIP SSI Percentage Calc. Grp.* v. *National Gov't Servs., Inc.*, No. 09-0939GC, 2015 WL 10371518, at *5 (PRRB Dec. 30, 2015); *Health All. Hospital Leominster, Mass.* v. *BlueCross BlueShield Ass'n/NHIC Corp.*, No. 06-0984, 2013 WL 11261923, at *7 (PRRB Sept. 24, 2013); *LAC ESRD Pre-Composite Rate Grp.* v. *BlueCross BlueShield Ass'n/Blue Cross of Cal.*, No. 92-0110G, 1999 WL 766795, at *9 (PRRB Sept. 21, 1999). When the PRRB can and does reject a CMS determination, that is strong evidence that the determination does not bind the agency and thus is not a "requirement" under Section 1395hh(a)(2). But those instances stand in stark contrast to the Medicare-fraction determination challenged here, which the PRRB understood to bind it. *See supra* pp. 15-16.

2. Tellingly, Petitioner's administrability fears have not materialized in the D.C. Circuit. The D.C.

Circuit in applying the decision below has not applied a blanket rule that all Medicare administrative materials issued by HHS and CMS now require notice and comment, as the Petitioner apparently fears. The D.C. Circuit has held that instructions in the Medicare Claims Processing Manual issued by CMS "do not alter the applicable legal standards" when those instructions "set forth an enforcement policy" only. *Clarian Health*, 878 F.3d at 354-356. The D.C. Circuit observed that, unlike the Part C days DSH policy here, "the agency maintains the same authority * * * that it had prior to the adoption of the Manual instructions" and the instructions neither "change the legal standards that govern the hospitals" nor "change the legal standards that govern the agency" because "the instructions bind neither CMS nor the Board in adjudications." *Id.* That is exactly right. And it confirms that CMS can operate under the test adopted below.

If anything, Medicare's regulatory process may run *more* efficiently under Section 1395hh(a)(2)'s relatively clearer "substantive legal standards" test. The uncertainty about when notice and comment is required under the APA's legislative–interpretive dichotomy, *supra*, pp. 13-14, pervades rulemaking challenges. "Even by the standards of administrative law—a field in which uniform, predictable rules of black-letter law are hard to come by—the resulting litigation is considered notoriously difficult." David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 Yale L.J. 276, 278 (2010). The D.C. Circuit's standard, under which notice and comment are required when the agency policy would change a substantive legal standard affecting the rights, duties, and powers of

regulated parties (Pet. App. 12a-14a), is more-definitive, providing more guidance to CMS policy-makers than the APA's amorphous tests and better aligned with the text of the Medicare statute. But at the very least, it will not grind the machinery of the Medicare system to a halt.

CONCLUSION

For the foregoing reasons, as well as those in Respondents' brief, the D.C. Circuit's judgment should be affirmed.

Respectfully submitted,

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